

1. (Amended) An autoclavable, non-flocculating aqueous suspension composition of a water insoluble or poorly soluble biologically active substance together with at least one phospholipid surface modifier and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, wherein the ratio of active substance to surface modifier and thermoprotecting agent is selected to provide particle size stability during and after terminal steam sterilization, and wherein a change in volume weighted particle size is not more than a two-fold increase subsequent to terminal steam sterilization.

B<sup>1</sup>  
2. (Amended) An autoclavable, non-flocculating aqueous suspension composition of a water insoluble or poorly soluble biologically active substance together with at least one phospholipid surface modifier and a pharmaceutically acceptable, water soluble polyhydroxy thermoprotecting agent, wherein the ratio of active substance to surface modifier and thermoprotecting agent is selected to provide particle size stability during and after terminal steam sterilization, wherein a change in volume weighted particle size is not more than a two-fold increase subsequent to terminal steam sterilization, and wherein the composition is substantially completely devoid of surfactants that require elevation of their cloud point temperature by addition of a cloud point modifier for further stabilization and substantially devoid of surfactant additives which cause destabilization of the formulation.

3. (Amended) The composition of claim 1 wherein the pH of the suspension before terminal steam sterilization is between about 5 to about 9 provided the pH value prior to terminal steam sterilization is selected such that the chemical stability of the suspension components is maintained during and after terminal steam sterilization .

4. (Amended) The composition of claim 1 wherein the composition also includes an amount of non-surfactant additives such that the composition attains an osmotic pressure acceptable for safe parenteral administration.

B<sup>1 cont</sup>  
5. (Amended) The composition of claim 1 wherein the composition also includes an amount of non-surfactant additive such that, on diluting the formulation with pharmaceutically acceptable diluent for parenteral administration to a pharmaceutically acceptable concentration for parenteral administration, osmotic pressure acceptable for safe parenteral administration of the diluted suspension results.

---

7. (Amended) The composition of claim 1 wherein the phospholipid surface modifier is selected from the group consisting of natural phospholipids and synthetic phospholipids.

B<sup>2</sup>  
8. (Amended) The composition of claim 7 wherein the natural phospholipid is an egg phospholipid or soy phospholipid.

9. (Amended) The composition of claim 1 wherein the amount of the phospholipid surface modifier provides a drug to surface modifier ratio of up to 5:1.

10. (Amended) The composition of claim 1 wherein the amount of phospholipid surface modifier is in the range from about 0.2% w/w to about 5.0% w/w.

---

B<sup>3</sup>  
12. (Amended) The composition of claim 1 wherein the active substance is an antifungal agent.

---

B<sup>4</sup>  
15. (Amended) The composition of claim 14 wherein the active substance is a cyclosporin.

16. (Amended) The composition of claim 1 wherein the active drug is a sterol.